ATTACHMENT 1

K130105 (1/2)

510(k) SUMMARY

MAY 17 2013

SUBMITTER'S NAME AND ADDRESS

DePuy Mitek
A Johnson & Johnson Company
325 Paramount Drive
Raynham, MA 02767

CONTACT PERSON

Julie Vafides
Regulatory Affairs Specialist II

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DATE PREPARED:	January 14, 2013

NAME OF MEDICAL DEVICE

TRADE NAME/PROPRIETARY NAME: RIGIDFIX® CURVE ST ACL PEEK Cross Pin System
RIGIDFIX® CURVE ST ACL PLA Cross Pin System

SUBSTANCIAL EQUIVALENCE

The proposed RIGIDFIX CURVE ST ACL Cross Pin System is substantially equivalent to the following devices:

- K974341 RIGIDFIX Femoral 3.3 mm ST Cross Pin Kit (PLA)
- K090669, K091041 RIGIDFIX Biocryl 3.3 mm Femoral ST Cross Pin Kit
- K103712 Gryphon PEEK Anchor

DEVICE CLASSIFICATION

PLA Implants: Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI, regulated under 21 CFR 888.3030.

PEEK Implants: Smooth or threaded metallic bone fixation fastener, classified as Class II, product code HTY, regulated under 21 CFR 888.3040.

Instruments: Orthopedic Manual Surgical Instruments, classified as Class I, product code LXH, regulated under 21 CFR 888.4540. The reusable instruments, although may individually be Class I devices, are only intended for use with the RIGIDFIX CURVE Cross Pin System implants, thus taking on the classification of the parent device (in this case, Class II).

FDA PRODUCT CODE: HTY, MAI

COMMON CLASSIFICATION NAME: Pin, Fixation, Smooth (HTY);
Fastener, Fixation, Biodegradable, Soft tissue (MAI)

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510(k) SUMMARY

DEVICE DESCRIPTION

The DePuy Mitek RIGIDFIX® CURVE Cross Pin System consists of instruments and Cross Pins designed for use with the RIGIDFIX® CURVE Cross Pin Instrumentation. The Soft Tissue (ST) Cross Pin material is PEEK™ (polyetheretherketone), a radiolucent high strength thermoplastic or PLA (Poly-Lactic Acid). Repair requires two (2) DePuy Mitek RIGIDFIX® CURVE Cross Pins.

INDICATIONS FOR USE

The DePuy Mitek RIGIDFIX® CURVE Cross Pin System is indicated for femoral fixation of autograft or allograft anterior cruciate ligament (ACL) soft tissue grafts.

TECHNOLOGICAL CHARACTERISTICS

The proposed RIGIDFIX CURVE ST ACL PLA Cross Pin System implant is identical in material and design to the predicate RIGIDFIX Femoral 3.3mm ST Cross Pin Kit implant which has previously received 510(k) clearance (K974341, K090669, K091041).

The proposed RIGIDFIX CURVE ST ACL PEEK Cross Pin System implant is manufactured out of PEEK (polyetheretherketone), a non-absorbable radiolucent high strength thermoplastic material. The same PEEK material is used in manufacturing the predicate DePuy Mitek Gryphon PEEK Anchor (K103712). Additionally, the RIGIDIFX CURVE ST ACL PEEK Cross Pin System implant has the same dimensional specification as the predicate RIGIDFIX Femoral 3.3mm ST Cross Pin Kit implant (K974341, K090669, K091041).

The proposed disposable (sleeves, trocar, bone gauge pin, and pusher rod) and reusable (guide frame, guide block, arc attachment and femoral rods) instruments for use with the RIGIDFIX CURVE Cross Pin System are similar to those currently offered for use with the predicate RIGIDFIX System (K974341, K090669, K091041). The proposed and predicate disposable and reusable instruments are made of similar materials: stainless steel and radel. The proposed disposable and reusable instruments have been redesigned to allow the capability of being fully adjustable for desired angle of femoral cross pin implantation. The predicate RIGIDFIX System only allows for the insertion of cross pins perpendicular to the graft (termed 0 degrees).

SAFETY AND PERFORMANCE

NONCLINICAL TESTING

Product Design Verification activities such as In-Vitro Break Strength Testing and Real-Time Break Strength Testing were performed on the implants. Results of performance and safety testing have demonstrated that the proposed devices are substantially equivalent to the predicate devices.

Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed RIGIDFIX CURVE Cross Pin System has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Depuy Mitek, a Johnson & Johnson Company
% Ms. Julie Vafides
Regulatory Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767

Letter dated: May 17, 2013

Re: K130105
Trade/Device Name: RIGIDFIX® CURVE ST ACL PEEK Cross Pin System
RIGIDFIX® CURVE ST ACL PLA Cross Pin System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, HTY
Dated: April 12, 2013
Received: April 15, 2013

Dear Ms. Vafides:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2
INDICATIONS FOR USE

510(k) Number (if known): K130105

Device Names: RIGIDFIX® CURVE ST ACL PEEK Cross Pin System
RIGIDFIX® CURVE ST ACL PLA Cross Pin System

Indications for Use: The DePuy Mitek RIGIDFIX® CURVE Cross Pin System is indicated for femoral fixation of autograft or allograft anterior cruciate ligament (ACL) soft tissue grafts.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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Casey L. Hanley, Ph.D.
Division of Orthopedic Devices